

REMARKS

Claims 1, 3-9 and 11-16 are pending. Claims 2 and 10 are cancelled as drawn to an unelected restriction group. Claims 1, 3-6, 8, 9, 11-13 and 16 are amended. Support for these amendments may be found throughout the Specification, in particular paragraph [0002]. What is claimed is not petroleum formed from organic material, underground, under pressure, over millions of years. This is plainly evident from the claims and the Specification. The claims have also been amended to clarify that the petroleum produced is “synthetic” in that the petroleum is a composition made by the action of transfected host microorganisms. The nature of the synthetic petroleum produced is explained in International Patent Application No. WO 0246446 [0002]. The translation of this reference’s parent Russian application is of record. Applicant submits that one of skill in the art would understand the petroleum of the original claim was synthetic petroleum analogous to that disclosed in WO 0246446 and not natural petroleum as defined on page 6 of the pending office action.

Issues outstanding in this application are as follows:

- The Title and Abstract are objected to.
- Claims 3 and 12 are objected to.
- Claims 1, 3, 9, and 11-16 are rejected under 35 U.S.C. 112, second paragraph, as indefinite.
- Claims 1, 3, 9, and 11-16 are rejected under 35 U.S.C. 112, first paragraph, as not enabled by the Specification in view of the skill in the art and the knowledge in the art.
- Claims 11-16 are rejected under 35 U.S.C. 102(b) as anticipated by Choi et al.
- Claims 1, 3 and 9 are rejected under 35 U.S.C. 103(a) as unpatentable over Kurashov et al. and Carroll et al.
- Claims 14-16 are rejected under 35 U.S.C. 103(a) as unpatentable over Choi et al. in view of Wigler et al.

I. TITLE & ABSTRACT

The Title and Abstract have been amended. Applicant requests the objection be removed.

II. CLAIM OBJECTIONS

Claim 3 has been amended to correct the spelling errors identified by the Examiner. Claim 12 has been amended to remove "starting." Applicant thanks the Examiner for helping to identify these obvious typographical errors and requests the objections be removed.

III. 35 U.S.C. 112, SECOND PARAGRAPH

A. Claims 1 and 3

Claim 1 has been amended to recite the step of combining the host microorganism with the solid fossil fuels or oil tars under conditions suitable for the conversion of the solid fossil fuels or oil tars into synthetic petroleum. Applicant requests the rejection be withdrawn.

B. Claim 9

Claim 9 has been amended to recite the step of combining the host microorganism with the solid fossil fuels or oil tars under conditions suitable for the conversion of the solid fossil fuels or oil tars into synthetic petroleum. Applicant requests the rejection be withdrawn.

C. Claims 11-15

Claim 11 has been amended to recite the step of combining the host microorganism with the carbon, hydrogen and oxygen under conditions suitable for the conversion of the carbon, hydrogen and oxygen into coal or synthetic petroleum. Applicant requests the rejection be withdrawn.

D. Claims 11-16 - Fossil Fuels

Claim 11 is now drawn to a method of converting carbon, hydrogen and oxygen into fossil fuels, including synthetic coal and or synthetic petroleum. Applicant requests the rejection be withdrawn.

E. Claims 1, 9 and 11 - Petroleum

The claims have been clarified in that the literal reading no longer implies that petroleum is made directly by a genetic engineering process. Applicant requests the rejection be withdrawn.

F. Claims 1, 3, and 9

The claims have been reformatted to clarify the relationship of (i) the solid fossil fuels (exemplified by coal) and (ii) the oil tars distilled from coal. The recitation of coal as an example of a solid fossil fuel has also been removed. Applicant requests the rejection be withdrawn.

G. Claim 12

Claim 12 has been amended to clarify the antecedent basis and to remove ~~or starting fossil fuel or oil tar~~. Applicant requests the rejection be withdrawn.

H. Claims 1, 9 and 11

The “including” phrases have been deleted. Applicant requests the rejection be withdrawn.

I. Claim 13

Claim 13 has been amended to remove “~~can exist in rocky, sandy or sand/water environments, can survive heat, cold, or....~~” Applicant respectfully submits one of skill in the

art would understand acid and basic as being above or below pH 7, respectively. *See* Office Action dated 22 Jan. 2007, pg 14, lines 15-16. Applicant requests the rejection be withdrawn.

IV. 35 U.S.C. 112, FIRST PARAGRAPH – ENABLEMENT

In order to make an Enablement rejection, the Examiner has the initial burden to establish a reasonable basis to question the Enablement provided for the claimed invention. MPEP 2164.04; *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993). In the pending rejection, the Examiner alleges various *Wands* factors weigh against enablement and concludes from this analysis that the Specification does not enable the claims. The amended claims clarify the scope of the claimed subject matter, thus, rendering parts of the Examiner's analysis inapplicable. Further, the Examiner's analysis is flawed in numerous ways and, thus, the Examiner does not put forward a reasonable basis to question the scope of Enablement.

Nature of the invention and breadth of claims

This *Wands* factor has been partially mooted by the amendment to claim 11 specifying “synthetic coal or synthetic petroleum” rather than “fossil fuels.” Applicant submits the breadth of the claims as amended are fully enabled.

Unpredictability of the Art and the State of The Art

The Examiner relies on the state of the art for ethanol production from biomass as indicating the art has had difficulty in elucidating viable ethanol production processes. The Examiner cited portion of Zaldivar et al. relates to the challenges in assembling “an efficient industrial configuration...before optimization and competitiveness are achieved.” Zaldivar et al. establishes the opposite of the Examiner's position in that ethanol production from biomass is described as old, well developed and technically viable (e.g. last sentence of Zaldivar et al. conclusion section). The same state of the art is taught by Lin et al. *E.g.* page 1, column 1, paragraph 2. The Examiner's misinterpretation of the prior art renders the analysis of this *Wands* factor erroneous.

Further, the Examiner's framework for analysis is legally erroneous. Enablement under 35 U.S.C. 112 does not turn on whether commercially competitive, industrial configurations are made directly possible by the teachings of the Specification. *CFMT, Inc. v. YieldUP International Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003) ("Enablement does not require an inventor to meet lofty standards for success in the commercial marketplace. Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect."); See also *Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 1562 (Fed. Cir. 1987) (citing *In re Strahilevitz*, 668 F.2d 1229, 1232 (CCPA 1982); *In re Gay*, 309 F.2d 769, 774 (CCPA 1962); *Douglas v. United States*, 510 F.2d 364, 366 (Ct. Cl.), *cert. denied*, 423 U.S. 825 (1975); *Trio Process Corp. v. L. Goldstein's Sons, Inc.*, 461 F.2d 66, 74 (3rd Cir.), *cert. denied*, 409 U.S. 997 (1972)):

Patents are not production documents, and nothing in the patent law requires that a patentee must disclose data on how to mass-produce the invented product. . . . The law requires that patents disclose inventions, not mass-production data, and that patents enable the practice of inventions, not the organization and operation of factories. Thus the law has never required that a patentee who elects to manufacture its claimed invention must disclose in its patent the dimensions, tolerances, drawings, and other parameters of mass production not necessary to enable one skilled in the art to practice (as distinguished from mass-produce) the invention. Nor is it an objective of the patent system to supply, free of charge, production data and production drawings to competing manufacturers. And that is well, for such a requirement would be irrational. Many inventions are never manufactured; the decision to manufacture may be taken well after the patent has issued; printing a thousand or more documents in the patent would often be required. For those and other reasons, the law requires that patents disclose inventions, not mass-production data, and that patents enable the practice of inventions, not the organization and operation of factories.

Quantity of Experimentation

The Examiner's analysis of this *Wands* factor amounts to an outline of various "parameters which would have to be studied to apply this technology...." and an unsupported assertion that work on the listed parameters would require "years of inventive effort." Office Action dated 22 Jan. 2007, pg 10. Again, the analysis is legally erroneous because it focuses on applying the claimed subject matter to commercially viable, industrial production (see immediately proceeding section).

Working Examples

Working Examples are not mandatory. However the Specification does provide a prophetic working example based on "Thiobacillus aquaesulis 4255 and 389, Thiosphaera pantotropha 356, Thiosphaera pantotropha 2944, and Thoibacillus thoioapar 55, or mutations or variant strains, to provide the tester sequences (all of which are described in International Patent Application No. WO 0246446), and other strains of the bacteria Thiobacillus aquaesulis, Thiosphaera pantotropha and Thoibacillus thoioapar which do not have this ability, to provide the driver sequences." [0008] A working example is not negated by the absence of a heading of "Prophetic Working Example" in the Specification. Again, the Examiner's analysis of this *Wands* factor is in error.

Guidance in the Specification

The Examiner's analysis of this *Wands* factor is rife with factual errors and misplaced legal concepts.

- The Examiner alleges the Specification provides no evidence that transfected microorganisms would be capable of converting coal, etc. into (synthetic) petroleum. This is a comment on the lack of working examples in the Specification evidencing a successful reduction to practice. As such, it relates to the immediately proceeding *Wands* factor. Prophetic examples, such as the one in described above are effective support absent a basis for disbelieving operability of the example. The Examiner makes no

argument to support an inoperability judgment against the prophetic working example. Hiding the relevant Examiner assessment under a different *Wands* factor does not avoid the Examiner's burden of providing a basis for questioning the operability of the prophetic example.

- The Examiner alleges the Specification provides no evidence that transfected microorganisms would be capable of converting coal, etc. into (synthetic) petroleum better than the starting microorganism. Again, this is properly dealt with under the *Wands* factor of Working Examples.
- Here the Examiner does attempt to supply a factual basis for questioning the ability to create transgenic microorganisms with improved production capabilities. However, the Examiner's alleged factual basis are incorrect. Ishizaki et al. does not report any recombinant *E. coli* results in Table 1. Applicant assumes the Examiner refers to Table 3. The Examiner's error is not so easily cured. Table 3 clearly discloses a P(3HB) productivity of $4.94 \text{ g l}^{-1} \cdot \text{h}^{-1}$ for recombinant *E. coli* versus 0.78 and $2.42 \text{ g l}^{-1} \cdot \text{h}^{-1}$ for what the Examiner identifies as the starting microorganisms. To whatever degree the Ishizaki et al. paper is relevant to the pending claims, the Examiner is mistaken as to the teachings of the reference.
- The Examiner similarly relies of Choi et al. Again the Examiner applies a legally erroneous framework of analysis based on commercial production goals that were not met by some forms of transgenic *E. coli*. Further, cited Figure 3 does not relate the productivity of the starter microorganisms. The Abstract discloses that native *A. latus* PHA biosynthesis is superior to transgenic *E. coli* carrying the PHA biosynthesis genes from *R. eutropha*. The comparison of productivity between native *A. latus* and transgenic *E. coli* carrying the PHA biosynthesis genes from *R. eutropha* is not relevant to the method of claim 9.
- Next, the Examiner states that the Specification amounts to an invitation to try and follow the teachings therein by following the complex procedure of gene identification,

transfection and determining appropriate culturing conditions. The Examiner also relates that one of skill in the art would understand the transgenes would likely include those to several enzymes. The Examiner's own argument provides proof of significant guidance in the Specification as viewed from the perspective of one of skill in the art. Practicing the claimed methods may require a sophisticated skill set, but that does not equate to a lack of guidance.

- Finally, the Examiner alleges that, after a thorough review of the art, the Examiner failed to find enabling teachings that would anticipate the claimed methods. This is noteworthy for two reasons. One, the absence of anticipatory art is not legally relevant to whether the Specification in view of the art enables the claimed methods for one of ordinary skill in the art. Two, the Examiner applies a 102(b) anticipation rejection in the same office action. This legally inapplicable and self contradicted argument highlights the inappropriate nature of the Examiner's pending enablement rejection.

Level of Skill in the Art

Applicant agrees that the level of ordinary skill in the art is very high. The skilled artisan will have a sophisticated understanding and complex skill set with which the artisan may reduce the claimed methods to practice without undue experimentation.

Conclusion

The Examiner summarizes the foregoing and not surprisingly pronounces the claimed methods non-enabled. Because the Examiner did not properly analyze the foregoing *Wands* factors, the Examiner has not provided a reasonable basis to question Enablement by the Specification. Applicant requests the rejection be withdrawn.

V. 35 U.S.C. 102(b) - Claims 11-16 are rejected under 35 U.S.C. 102(b) as anticipated by Choi et al.

Claim 11 has been amended to a method of converting carbon, hydrogen and oxygen into synthetic coal or synthetic petroleum. P(3HB) is neither synthetic coal nor synthetic petroleum and thus Choi et al. does not anticipate the pending claims. Applicant requests the rejection be withdrawn.

VI. 35 U.S.C. 103(a)

A. Claims 1, 3 and 9 are rejected under 35 U.S.C. 103(a) as unpatentable over Kurashov et al. and Carroll et al.

1. *Graham* Factors

Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), controls the consideration and determination of obviousness under 35 U.S.C. 103(a); *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734-35, 167 L. Ed. 2d 705, 715 (U.S. 2007).

The four factual inquires enunciated therein as a background for determining obviousness are as follows:

1. Determining the scope and contents of the prior art;
2. Ascertaining the differences between the prior art and the claims in issue;
3. Resolving the level of ordinary skill in the pertinent art; and
4. Evaluating evidence of secondary considerations.

Based on these factual inquires, the Examiner has the burden of establishing a *prima facie* case for an obviousness. To establish *prima facie* obviousness the Examiner must identify and explain the reasons why one of ordinary skill in the art would have derived the claimed subject matter and why one of ordinary skill in the art would have a reasonable expectation of success.

KSR International Co. v. Teleflex, Inc., 127 S. Ct. 1727, 1741, 167 L. Ed. 2d 705, 722 (U.S. 2007) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness," quoting *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006)); *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1360-61 (Fed. Cir. 2006); *In re Lee*, 277 F.3d 1338, 1341, 1344-45 (Fed. Cir. 2002); See also Memorandum from Margaret A. Focarino et al. to Technology Center Directors re Supreme Court Decision on *KSR Int'l Co. v. Teleflex, Inc.* (USPTO May 3, 2007).

The level of ordinary skill in the art is high as discussed above for enablement and is not contested. Secondary consideration are not at issue in this appeal because the claims are not properly rejected as *prima facie* obvious.

2. Determining the scope and contents of the prior art

Carroll et al. is an overview of basic molecular biology techniques. The Examiner distorts these generic teachings as discussed below. In addition, the Examiner alleges that Carroll et al. discloses using an oligonucleotide probe corresponding to one organism's gene to identify homologous coding sequences from other organisms by hybridization (first sentence, pg. 16). Applicant cannot find this teaching and the Examiner does not identify it with any specificity. To the degree the obviousness rejection is predicated on this nonexistent teaching, the rejection is improper.

3. Ascertaining the differences between the prior art and the claims in issue

The Examiner on page 15 relates that Carroll et al. teaches "isolating a starting microorganism capable of converting one material into another, such as amino acids into proteins...." This is a thinly veiled attempt to cast Carroll et al. as more than a generic overview of recombinant DNA technology. In essence, the Examiner is stating that creating transgenic organisms capable of transgene protein production is the same as creating transgenic organisms capable of (synthetic) petroleum production. Applicant does not agree that there is a logical

correlation between transgene driven protein production and transgene driven petroleum production.

4. Reasoning supporting the determination of obviousness

Finally, the Examiner lays out the reasoning supporting the Examiner's determination of obviousness. The Examiner, on page 16 of the pending office action, points to the teachings of Carroll et al. as supplying an express motivation to derive the claimed methods, specifically:

The motivation to do so is provided by

Carroll et al who teach: "The overall goal of recombinant-DNA technology is to identify, isolate, manipulate, and re-express genes from a given host (1-9). Some of the practical goals of such cut-and-paste technology is to 1) develop a basic understanding of the function and regulation of known gene products. 2) identify new genes whose protein products have not been isolated (reverse genetics). 3) correct endogenous genetic defects (eg. sickle cell anemia). 4) express foreign genes in disease-susceptible hosts (eg. Disease resistance genes in agricultural crops). and 5) manufacture large quantities of a protein product for widespread use" (see Introduction).

This introduction to Carroll et al. is a recitation of a generic use for recombinant-DNA technology and several specific applications. The claimed methods are not directed to generic cloning procedures, developing a basic understanding of the function of known gene products, reverse genetics, gene therapy, transgenic disease resistance, or large scale protein production. The Examiner has therefore not provided any reasoning supporting the determination of obviousness of the claimed methods.

It is clear from the above that the Examiner has distorted or simply made up the alleged teachings of Carroll et al. to form a classic hindsight reconstruction. The hindsight nature of the rejection is made plain by the absence of any reasoning explaining how and why one of ordinary

skill in the art would have derived the claimed methods. Because the rejection is facially deficient, Applicant requests the rejection be withdrawn.

B. Claims 14-16 are rejected under 35 U.S.C. 103(a) as unpatentable over Choi et al. in view of Wigler et al.

This rejection is expressly predicated on the anticipation rejection over Choi et al. As discussed above, the clarified claims are not anticipated by Choi et al. Consequently, this derivative obviousness rejection is likewise no longer applicable. Applicant requests the rejection be withdrawn.

VII. CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance. Three months' extension of the response deadline is requested and the fee therefore co-submitted. Applicant believes no other fee is due with this response. However, if a fee is due, please charge Deposit Account No. 06-2375, under Order No. HO-P03493US0 from which the undersigned is authorized to draw.

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Respectfully submitted,

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